

**REMARKS**

Reconsideration and withdrawal of the rejections of this application are respectfully requested in view of the amendments and remarks herewith.

This invention provides improved paste formulations suitable for pharmaceutical and veterinary use containing an effective amount of a polymorphic B Form of 3-(cyclopropylmethoxy)-4-[4-(methylsulfonyl)phenyl]-5,5-dimethyl-5H-furan-2-one, fumed silica, as a thickening agent, and a viscosity modifier to increase the viscosity of the paste.

The Examiner in pending application 10/117,854 found polymorphic B Form of 3-(cyclopropylmethoxy)-4-[4-(methylsulfonyl)phenyl]-5,5-dimethyl-5H-furan-2-one to be allowable subject matter. Specifically, the Examiner found that the prior art does not teach or fairly suggest the claimed form of the compound.

Further, it has been surprisingly found that the addition of a viscosity modifier increases the viscosity of the paste, while reducing the total amount of fumed silica. Moreover, the inventive formulations exhibit good physical stability over the shelf life and retain good chemical integrity, texture, consistency and viscosity over a wide temperature range used for the polymorphic B Form of 3-(cyclopropylmethoxy)-4-[4-(methylsulfonyl)phenyl]-5,5-dimethyl-5H-furan-2-one.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 65-73 are pending by this paper. Claims 50-64 are cancelled and new claims 65-73 added without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support is found throughout the specification and from the originally pending claims. And, in view of the restriction

requirement, the claims presented herewith do not represent any narrowing of the claims. Hence, there should be no estoppel by this paper.

**II. THE REJECTIONS UNDER 35 U.S.C. § 112,  
1<sup>ST</sup> AND 2<sup>ND</sup> PARAGRAPH, ARE OVERCOME**

Claims 50-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which allegedly does not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These rejections are moot as claims 50-64 are canceled.

Claims 50-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These rejections are moot as claims 50-64 are canceled.

It is to be noted the term "lake" is well known in the art as a colorant and one of ordinarily skill would understand "lake" in the present application to be interpreted as such. See, 21 C.F.R. Part 70, Color additives, .3(l) ("The term lake means a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing processes."); See also, Lynn A. Kuntz, *Colors Au Nature*, Weeks Publishing Company (1998), at <http://www.foodproductdesign.com/archive/1998/0398AP.html> ("FD&C lakes are often thought to be oil-soluble. However, they actually color by dispersion; they are insoluble in oil or water.")

Consequently, the rejections under Section 112, first and second paragraph, should be reconsidered and withdrawn; and, such relief is respectfully requested.

**III. THE REJECTION UNDER SECTION 103 ARE OVERCOME**

Claims 50-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,698,584 to Black et al., U.S. Patent Nos. 5,981,576 to Belley et al. or 6,020,343 to Belley et al. taken with U.S. Patent No. 6,017,520 to Synodis et al. and U.S. Patent No. 5,958,458 to Norling et al. or U.S. Patent No. 5,880,076 to Vermeer et al. and Norling et al. or U.S. Patent No. 5,266,304 to Baffelli et al. and Norling et al. The rejection is respectfully traversed. None of the numerous documents, either alone or in combination, teaches, suggests or discloses the present invention.

Applicant's invention is directed to, *inter alia*, an improved paste formulation suitable for pharmaceutical and veterinary use containing polymorphic B Form of 3-(cyclopropylmethoxy)-4-[4-(methylsulfonyl)phenyl]-5,5-dimethyl-5H-furan-2-one, fumed silica, as a thickening agent, and a viscosity modifier to increase the viscosity of the paste. It is respectfully urged that rejection under Section 103 be reconsidered and withdrawn as polymorphic B Form of 3-(cyclopropylmethoxy)-4-[4-(methylsulfonyl)phenyl]-5,5-dimethyl-5H-furan-2-one recited in new claims 65-73 has already been examined and deemed allowable in a co-pending application, as discussed above.

Specifically, the Examiner in pending application 10/117,854 found polymorphic B Form of 3-(cyclopropylmethoxy)-4-[4-(methylsulfonyl)phenyl]-5,5-dimethyl-5H-furan-2-one to be allowable subject matter. More specifically, the Examiner found that the prior art does not teach or fairly suggest the claimed form of the compound. Each of new claims 65-73 is directed to a novel pharmaceutical or veterinary paste formulation comprising the above polymorphic B Form therapeutic agent, a fumed silica, as a thickening agent, and a viscosity modifier to increase the viscosity of the paste.

None of the cited documents suggests the superior viscosity and stability and ease of preparation that results from the combination of fumed silica, the viscosity modifier and polymorphic B Form of 3-(cyclopropylmethoxy)-4-[4-(methylsulfonyl)phenyl]-5,5-dimethyl-5H-furan-2-one.

Therefore, it is respectfully requested that the rejection under section 103 be reconsidered and withdrawn.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, an interview with the Examiner and his SPE is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

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CONCLUSION

In view of the remarks and amendments herewith and those of record, and the matters discussed during the interview, the application is in condition for allowance.

Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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